REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Status of the Claims

Claims 1-26 were previously cancelled. Claims 52-53 and 108-109 are cancelled in this response without prejudice or disclaimer thereof. Claims 27 and 87 have been amended to recite that the active agent is not ketoprofen or naproxen. Original claims 52-53 and 108-109 support these amendments. Claims 28, 50 and 106 have been amended to set forth the subject matter more clearly.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 27-51 and 87-107 will be under examination, with claims 54-86 and 110-111 withdrawn.

II. Rejection of Claims under 35 U.S.C. § 112, second paragraph

Claims 27-53 and 87-109 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Applicants respectfully traverse the rejection.

Specifically, the Examiner rejects claims 27-28 and 87 for the recitation of "substantially." The claims have been amended to delete the term in question, thereby obviating the basis for the rejection.

III. Rejection of Claims under 35 U.S.C. § 102 (b) or (e)

A. Eickhoff

Claims 27-34, 37-47, 50-53, 87-93 and 96-109 are rejected under 35 U.S.C. § 102(b) for alleged anticipation by U.S. Patent No. 5,518,738 to Eickhoff *et al.* ("Eickhoff"). Applicants respectfully traverse the rejection.

Eickhoff discloses a composition comprising a crystalline NSAID, such as ketoprofen and naproxen, having polyvinylpyrrolidone adsorbed on the surface thereof, hygroscopic sugar and sodium lauryl sulfate. The composition of Eickhoff exhibits greatly reduced gastric irritation and/or hastened onset of action (abstract).

By contrast, the claimed invention relates to an oral solid dose comprising a solid dose matrix. The solid dose matrix comprises at least one pharmaceutically acceptable water-soluble or water-dispersible excipient, and within the solid dose matrix there is a nanoparticulate active agent composition comprising a poorly soluble active agent that is NOT ketoprofen or naproxen and at least one surface stabilizer, as recited in claims 27 and 87. The claimed formulation rapidly disintegrates upon contact with saliva in less than three minutes.

The Examiner acknowledges that "Eickhoff is silent about such [a] characteristic or property of the surface stabilizer or the formulation," but asserts that "such [a] property or characteristic [is] deem[ed] to be inherent to the referenced composition since the essential components of Eickhoff are identical to the instant composition" (Office Action, page 4, lines 14-20). However, the "essential components" of Eickhoff are not identical to the claimed composition, as the claimed composition, as amended, excludes ketoprofen and naproxen. Thus, because Eickhoff does not teach the specific formulation of the claimed invention, one would not expect the prior-art formulation to have the inherent characteristic of rapid disintegration required by the claimed composition. Accordingly, Eickhoff does not anticipate the claimed invention.

B. Kerkhof

Claims 27-48, 50-53 and 87-109 are rejected under 35 U.S.C. § 102(e) for alleged anticipation by WO 01/45674 by Kerkhof *et al.* ("Kerkhof"). Applicants respectfully traverse the rejection.

Kerkhof describes a technique that is able to produce stable nanometer particles of a poorly water-soluble or substantially water-insoluble compound (page 6, lines 2-6). Kerkhof explicitly teaches that "[b]y stable, it is meant that the dispersion exhibits no flocculation or particle agglomeration visible to the naked eye at least fifteen minutes, and preferably, at least two days or longer after preparation" (page 8, lines 3-5). Therefore, the "stability" property of Kerkhof's formulation is irrelevant to "rapid disintegration" of the claimed composition.

Moreover, Kerkhof does nothing more than provide a laundry list of choices and combinations of the nonsoluble drug ingredients, carrier excipients, and surface stabilizers. The reference dos not provide any teaching, suggestion or motivation as to what specific ingredients to combine, and how and in what proportion, to arrive at a composition that would have the disintegration parameters as presently claimed.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b) or (e).

IV. Rejection of Claims under 35 U.S.C. § 103 (a)

Claim 49 is rejected under 35 U.S.C. § 103(a) for alleged obviousness over Eickhoff or Kerkhof, and further in view of the specification, at page 3, lines 13-22. Applicants respectfully traverse the rejection.

For the reasons stated above, neither Eickhoff nor Kerkhof teaches or fairly suggests the claimed invention. The Examiner cites the portion of the specification describing a freeze-dried

drug dosage form. This alleged teaching does not compensate for the deficiencies of Eickhoff and Kerkhof, as detailed above. Therefore, claim 49 is non-obvious over the cited art because the base claim that it depends from is non-obvious.

V. Nonstatutory Double Patenting Rejections

Claims 27-53 and 87-109 are rejected under the judicially created doctrine of double patenting over claims 1-24 and 51-70 of U.S. Patent No. 6,316,029. Claims 27-53 and 87-109 are rejected under the judicially created doctrine of double patenting over claims 1-16 and 21 of U.S. Patent No. 6,165,506. Applicants choose to defer any action until the Examiner indicates that the pending claims are allowable.

The Examiner also requests that Applicants review copending application Serial Nos. 10/444,066, 11/274,069, 11/592,264 and 09/337,675 and "submit the appropriate Terminal Disclaimer(s)." Because the Examiner has not met the initial burden to impose any obviousness-type double patenting rejection, Applicants cannot respond to any non-existing rejection by submitting terminal disclaimers. Accordingly, Applicants respectfully request the to Examiner elaborate on the rejection to be made over the copending '066, '069, '264 and '675 applications.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper

or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 12/13/07

By _____

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